

Components

Sample Table 1

Definition of Component: A component is a full consortium member of a MBCCOP. A consortium agreement (letter) between the MBCCOP organization and each component must be included in the application. OHRP assurance requirements must be met (see MBCCOP RFA, A.Terms and Conditions of Award, 1. MBCCOP Awardees Responsibilities, Sec. (m.) Federally Mandated Regulatory Requirements).

Directions:

Column (2) Indicate if component is a hospital, group/office practice, or other organization (indicate type). If hospital, indicate all applicable codes: 1=Not for Profit; 2=Federal Government (VA or MTF); 3=For Profit; 4=State/County/City Government; 5=Teaching 6=Medical School; 7=Approved Residency; 8=Formal Medical Affiliation with Student Rotation.

(3) Indicate if hospital has a current American College of Surgeons (ACOS) accredited cancer program.

(5) Use new cases diagnosed or receiving primary treatment at that hospital or physicians group, practice except for basal cell or squamous cell carcinoma of the skin.

(6) Indicate OHRP CPA, MPA or FWA number.

(1) Name of Component Address Telephone Number	(2) Description		(3) ACOS Accredited Program Yes/No	(4) Total Number of Hospital Beds (Hospital Only) 2004	(5) Number of New Cancer Patients (In/Out patient) 2002 2003		(6) OHRP Assurance Number
	H=Hospital G=Group O=Other	If Hospital enter applicable codes (see above)					

Affiliates

Sample Table 2

Definition of Affiliate: Occasionally, a MBCCOP may want to establish a relationship with an organization that may be able to put a minimum number of patients on protocols but for which full consortium membership is not appropriate. OHRP assurance requirements must be met (see MBCCOP RFA, A.Terms and Conditions of Award, 1. MBCCOP Awardees Responsibilities, Sec. (m.) Federally Mandated Regulatory Requirements).

Directions: Column (2) Indicate if affiliate is a hospital, group/office practice, or other organization (indicate type). If hospital, indicate all applicable codes: 1=Not for Profit; 2=Federal Government (VA or MTF); 3=For Profit; 4=State/County/City Government; 5=Teaching 6=Medical School; 7=Approved Residency; 8=Formal Medical Affiliation with Student Rotation.

(3) Indicate if hospital has a current American College of Surgeons (ACOS) accredited cancer program.

(5) Use new cases diagnosed or receiving primary treatment at that hospital or physicians group, practice except for basal cell or squamous cell carcinoma of the skin.

(6) Indicate OHRP CPA, MPA or FWA number.

(1) Name of Affiliate Address Telephone Number	(2) Description		(3) ACOS Accredited Program Yes/No	(4) Total Number of Hospital Beds (Hospital Only) 2004	(5) Number of New Cancer Patients (In/Out patient)		(6) OHRP Assurance Number
	H=Hospital G=Group O=Other	If Hospital enter applicable codes (see above)			2002	2003	

Participating Physicians

Sample Table 3A

Directions:

- Column:
- (1) Group by component/affiliate with which physician is affiliated. If a physician is affiliated with multiple components, list him/her only with primary component.
 - (2) List all physicians who will participate in your MBCCOP, then indicate:
 - (3) Type of practice: Group=G; Solo=S; or Hospital-Based =H.
 - (4) Type of participation: enter "A" if the physician is expected to enter patients on NCI-approved protocols or "B" if the physician will be aware of protocol requirements and actively support the MBCCOP but will not be actually registering patients (e.g., a pathologist or a diagnostic radiologist).
 - (5) Physician's year of graduation from medical school.
 - (6) Physician's specialty/subspecialty.
 - (7) Indicate whether physician is board-certified or board-eligible for specialty.

(1) Component/ Affiliate	(2) Physician's Full Name	(3) Practice Type G/S/H	(4) Type Partic. A/B	(5) Grad. Year	(6) Specialty/ Subspecialty	(7) Board	
						Cert.	Elig.

- Directions:
- (1) Group by component/affiliate with which individual is affiliated. If an individual is affiliated with multiple components, list him/her only with primary component.
 - (2) List all non-physician investigators responsible for patients/participants on cancer prevention and control trials in your MBCCOP.
 - (3) List highest degree attained.
 - (4) Enter the year the highest degree was confirmed.
 - (5) Individual's specialty/discipline.

(1) Component/ Affiliate	(2) Individual's Full Name	(3) Highest Degree	(4) Year Degree Confirmed	(5) Specialty/ Discipline

All Other Personnel

Sample Table 4

Directions: List all personnel (e.g., MBCCOP administrator/coordinator, clinical research associates, data managers, nurses) who will participate in the MBCCOP activities. Indicate MBCCOP component/affiliate with which person is most closely associated. Please complete all columns.

(1) Component/Affiliate	(2) Individual=s Full Name	(3) Check if R.N.	(4) Highest Academic Degree	(5) Position	(6) Proposed Hrs/Week on MBCCOP Activities

Number of Newly Diagnosed Cancer Patients By Site

Sample Table 5

Directions: Provide figures for the table below to the extent possible. Use new cases diagnosed or receiving treatment at that hospital, except for basal cell or squamous cell carcinoma of the skin. Submit a separate sheet for each hospital component.

Name of Component: _____

Information Source: ☐ Hospital Registry ☐ Regional Registry ☐ Population Based Registry
☐ Hospital Discharge Data ☐ Other

	Calendar Year 2002 2003			Calendar Year 2002 2003	
Breast Tumor			Non-Small Cell Lung		
Esophagus			Hodgkin=s Disease		
Stomach			Non-Hodgkin=s Disease		
Pancreas			Kaposi=s Sarcoma		
Hepatobiliary			Melanoma		
Colon			Head/Neck Tumors		
Rectum			Brain/Other CNS Tumors		
GI (other)			Endocrine		
Bladder			Osteogenic Sarcoma		
Kidney			Soft Tissue Sarcoma		
Prostate			Rhabdomyosarcoma		
Testis			Ewing=s Sarcoma		
GU (other)			Sarcoma (other)		
Cervix			Wilm=s Tumor		
Ovary			Neuroblastoma		
Uterus, Endometrial			Pediatric ALL		
GYN (other)			Pediatric AML		
Myeloma			Pediatric Acute Leukemia (other)		
Adult Acute Lymphocytic Leukemia			Pediatric Lymphomas incl. Hodgkin=s Disease		
Adult Acute Non-Lymphocytic Leukemia			Pediatric Solid Tumors/Others		
Chronic Leukemia			Other		
Small Cell Lung					

Total:

Cancer Treatment Research Participation - NCI Approved Protocols
Sample Table 6A

Directions; **Column:** (1) Indicate if currently participating in MBCCOP (Yes or No).
 (3) Indicate protocol source: name of cooperative group or cancer center.
 (4) Code the accrual by predominant practice mode for a given year:
 private practice = P; salaried academic = A; training/fellowship = F.

This table is intended to reflect current entries and is not a substitution for the total treatment accrual in the progress report (if applicable). For all current and projected physicians, please list accrual by physician to all NCI-approved studies (e.g.: Cooperative Group/Cancer Center Research Bases).

(1) Names of Existing MBCCOP Physicians* and Proposed Participating Physicians	(2) MBCCOP Phys. (Y/N)	(3) Protocol Source	(4) Number of Patients Entered		
			6/01-5/02	6/02-5/03	6/03-5/04
Example: Jane R. Doe, MD	Y	NSABP	0/F	13/F	20/A

Page Totals:

Existing MBCCOP Physicians:*

All Physicians:

Grand totals (last page only):

Existing MBCCOP Physicians

All Physicians:

* Applies to continuing applicant only

Narrative explanation may be attached if needed to fully document your experience.

Directions:
Column: (2) Indicate if currently participating in MBCCOP (Yes or No).
(3) Indicate protocol source: may be single institution studies, drug companies, local hospitals, or others.
(4) Code accrual by predominant practice mode for given year:
private practice = P; salaried academic = A; training/fellowship = F.

For all current and projected physicians, please list accrual by physician to all other protocols (e.g.: pharmaceutical studies, etc.)

(1) Names of Existing MBCCOP Physicians* and Proposed Participating Physicians	(2) MBCCOP Phys. (Y/N)	(3) Protocol Source	(4) Number of Patients Entered		
			6/01-5/02	6/02-5/03	6/03-5/04
Example: Jane R. Doe, MD	Y	Eli Lilly	0/F	5/F	10/A

Page Totals:

Existing MBCCOP Physicians:*

All Physicians:

Grand totals (last page only):

Existing MBCCOP Physicians

All Physicians:

* Applies to continuing applicant only
Narrative explanation may be attached if needed to fully document your experience.

Cancer Prevention and Control Research Participation - NCI Approved Protocols Sample Table 6C

Directions:

- Column (2) Indicate if currently participating in MBCCOP (Yes or No).
 (3) Indicate protocol source: name of cooperative group; cancer center; other organization
 (4) Code the accrual by predominant practice mode for a given year:
 private practice = P; salaried academic = A; training/fellowship = F.

This table is intended to reflect current and proposed entries and is not a substitution for the total cancer prevention and control accrual in the progress report (if applicable). For all current and projected physicians, please list accrual by physician to all NCI approved studies (e.g.: Cooperative Group/Cancer Center Research Base protocols).

NOTE: For studies other than MBCCOP Research Base studies, please fill out Sample Table 7C.

(1) Names of Existing MBCCOP Physicians* and Proposed Participating Physicians	(2) MBCCOP Phys. (Y/N)	(3) Protocol Source	(4) Number of Participants Entered		
			6/01-5/02	6/02-5/03	6/03-5/04
Example: Jane R. Doe, MD	Y	NSABP	0/F	13/F	20/A

Page Totals:

Existing MBCCOP Physicians:*

All Physicians:

Grand totals (last page only):

Existing MBCCOP Physicians

All Physicians:

* Applies to continuing applicant only

Narrative explanation may be attached if needed to fully document your experience.

Directions: Information to be provided as part of the Progress Report (for prior funding period of up to 5 years) for applicants submitting competing continuation applications.

- Column (1)
- Indicate protocol source: name of MBCCOP Research Base.
- Column (2)
- Indicate the total number of patients and the credit equivalent entered onto NCI approved cancer treatment clinical trials.

(1) MBCCOP Research Base	(2) Number of Patients - Credits									
	6/99 - 5/00		6/00 - 5/01		6/01 - 5/02		6/02 - 5/03		6/03 - 5/04	
	Patients	Credits	Patients	Credits	Patients	Credits	Patients	Credits	Patients	Credits
Example: SWOG	63	63	75	75	60	55	80	80	75	70

Total Table 7A: _____

Directions: Information to be provided as part of the Progress Report (for prior funding period of up to 5 years) for applicants submitting competing continuation applications.

- Column (1)** Indicate protocol source: name of MBCCOP Research Base.
(2) Indicate the total number of new entry credits & follow-up (FU) credits for accrual to NCI approved cancer prevention and control clinical trials.

Special Instruction:

Please list the Breast Cancer Prevention Trial (BCPT), the Prostate Cancer Prevention Trial (PCPT), the Study of Tamoxifen and Raloxifene (STAR) and the Selenium and Vitamin E Trial in Prostate Cancer Prevention (SELECT) on separate lines.

(1) MBCCOP Research Base	(2) New Entry Credits & Followup Credits									
	6/99 5/00		6/00 5/01		6/01 5/02		6/02- 5/03		6/03- 5/04	
	New Entry Credits	FU Credits	New Entry Credits	FU Credits	New Entry Credits	FU Credit	New Entry Credits	FU Credits	New Entry Credits	FU Credits
Example: SWOG	20	0	10	0	25	0	10	0	15	1
Example: BCPT	20	0	30	6	30	15	25	24	0	31.5
Total Table 7B:										
Total Credits/Year (New & FU):										

Narrative explanation may be attached if needed to fully document your experience.

Participation in Cancer Prevention and Control Research Studies supported through other Federally Funded Mechanisms (e.g., research project grants (R01), contracts)

Sample Table 7C

Directions: If applicable, provide the following information regarding the MBCCOP=s participation in cancer prevention and control research supported by other federally funded mechanisms.

- Column**
- (1)** Indicate Federally Funded Mechanism (e.g., grant, contract)
 - (2)** Provide Title of the Study. Designate as either (C)= Currently Active; and/or (P) = Planned for Proposed Funding Period.
 - (3)** Briefly describe primary involvement/participation in the research study
 - (4)** Provide number of participants accrued for the period June 2003 through May 2004.
 - (5)** Provide projected number of participants for proposed funding period.

(1) Federally Funded Mechanism e.g. R01CA12345, N01CN12345	(2) Title of the Research Study <u>Designate as either:</u> (C) Currently Active; and/or (P) Planned for Proposed Funding Period	(3) Primary Involvement in Research Study **	(4) Number of Participants accrued (6/03-5/04)	(5) Number of Proposed Participant Accruals
Example: R01CA11111	(C) Home Care Training for Breast Cancer Patients	Accrue participants and refer to institution performing centralized delivery of the intervention (e.g., via telephone).	15	
Example: R01CA12345	(C) Smokeless Tobacco--Nicotine Patch & Self Help Treatment	Accrue participants and deliver intervention	23	
Example: N01CN12345	(P) Phase II Trial of DFMO in Cervix	Accrue participants, monitor data	N/A	10

**** Narrative explanation may be attached if needed to fully document your experience.**

Directions: See MBCCOP RFA, A. Terms and Conditions of Award for MBCCOP Awardees,
1. MBCCOP – Awardees Responsibilities, b. Research Base Affiliation(s).

Name of Research Base	Name & Location of Intermediary Institution, if Applicable	Treatment Research Yes/No	Cancer Prevention and Control Research Yes/No

In the narrative, describe previous working relationships with proposed research base, if applicable. Include information on committee memberships and chairmanships as well as protocols chaired. If one or more components participated as cooperative group affiliate program satellite hospitals, specify the years.

Limit to two pages.

Directions: Organize by Research Base(s). Use separate page(s) for each Research Base.

Name of Research Base: _____

This table should reflect the entire anticipated MBCCOP treatment accrual for the coming year.

(1) Protocol Title	(2) NCI Protocol Number	(3) Disease Site	(4) Anticipated Patient Accrual		
			Patients Available	Patients to be Placed on Study	Accrual Credits

Subtotal for Research Base:

Grand Total (last page only):

Directions: Organized by research base(s). Use separate page(s) for each research base.

Name of Research Base: _____

This table should reflect the entire anticipated MBCCOP prevention and control accrual for the coming year.

(1) Protocol Title	(2) NCI Protocol Number	(3) Disease Site	(4) Anticipated Participants Accrual		
			Participants Available	Participants to be Placed on Study	Accrual Credits

Subtotal for Research Base:

Grand Total (last page only):